IN THE DISTRICT COURT OF THE UNITED STATES
DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

UNITED STATES OF AMERICA,	)	2:11-CR-511
Plaintiff	)	Charleston,
	)	South Carolina
VS	)	November 10, 2014
JIAN-YUN DONG, et al,	)	
Defendants	)	

TRANSCRIPT OF TESTIMONY OF
DR. PATRICIA REPIK-BYRNE
BEFORE THE HONORABLE C. WESTON HOUCK,
SENIOR UNITED STATES DISTRICT JUDGE

APPEARANCES:

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Proceedings recorded by mechanical shorthand, Transcript produced by computer-aided transcription.

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MR. KLUMB: The Government calls Patricia Repik.

THE CLERK: Please raise your right hand and place your left hand on the Bible.

Please state your name for the record and spell your last name.

THE WITNESS: My name is Patricia Repik-Byrne. Spelling of the last name is R E P, as in Peter, I K, then a hyphen, B as in boy, Y R N E.

THEREUPON:

MS. PATRICIA REPIK-BYRNE,

Called in these proceedings and after having been first duly sworn testifies as follows:

THE CLERK: Thank you. You may have a seat over there.

DIRECT EXAMINATION

BY MR. KLUMB:

Q. Is it okay if I just refer to you as Dr. Repik?

A. Yes.

Q. Thank you. Dr. Repik, where are you currently employed?

A. Currently employed at United -- at, um, National Institutes of Health in Maryland.

Q. Okay. Is there a subunit that you are working for or --

A. Yeah. So it's National Institute of Allergy and Infectious Diseases.

Q. And NIAID?

A. NIAID.

Q. What is your position there currently?

A. I'm a Program Officer for emerging viral diseases in the virology branch.

Q. And how long have you been doing that?

A. So I have been there since April of 2002. So it's a little over 12 years.

Q. And can you generally describe for the jury what your duties and responsibilities are in that position?

A. Okay. So Program Officer kind of oversees grants that have to do with different diseases or conditions that NIH is working on. So the National Institute of Allergy Infectious Diseases, there is a lot of different departments. And the department that I'm in represents viruses.

And so different program officers oversee different virus projects. And the projects I oversee are viruses that cause encephalitis, like West Nile, encephalitis, or causes hemorrhagic fever, like E-Bola, Marburg, Yellow Fever. So I handle a lot of the projects that are dealing with those kinds of things.

And the projects that I handle -- everybody is a little bit different -- but the projects I handle go from -- anywhere from basic research, where they are really trying to find out, you know, what -- how these viruses actually work,

how they infect the body, how you develop antibodies against them, and then also up until product development. So -- and I also handle projects that deal with developing therapeutics or vaccines or any therapeutics. So it's pretty broad.

Q. Can you give us some idea about your caseload? Approximately how many grants or projects do you oversee?

A. So I oversee basically approximately 125 to 130 projects.

Q. And since 2002 has your caseload been roughly the same or does it go up and down?

A. It goes up and down a little bit. It went up a bit when we had, you know, some influx of money, when President Obama, you know, had a little bit more money, about 2009 or 2010. So now it's gone down a little bit. But it's roughly been about 125 to 130, roughly, over the years.

Q. Okay. Please give us a little bit of information about your technical background. What kind of degrees do you have?

A. So I have a bachelor's degree, then I went on to get a Ph.D. degree. So my bachelor's degree is in microbiology and chemistry. And then my Ph.D. degree is in virology and viruses.

Q. And what did you do before you came to NIAID?

A. So before I came to NIAID, I had various jobs. So I had worked -- after I got my degree, I did post-doctoral work in viruses, on Dengue virus, and that was at the Walter Reed Army Institute of Research down in Washington D.C. And then

our whole laboratory went up to USAMRIID, which is United States Army Medical Research Institute of Infectious Diseases in Fredericktown. So I worked there for quite a number of years, for about six or so years. And then I left there to take a position up in Philadelphia. So I became Assistant Professor in medical school in Philadelphia, the Medical College of Pennsylvania, which originally was Women's Medical College. So I was there for about nine years. And after that, I went into doing some work in biosafety testing companies. So I had worked in three small companies.

Every time that a company is trying to develop a product, it has to go through certain kinds of testing that the FDA requires. And so I was at one of these testing companies. I was at a couple of testing companies overseeing the different kinds of tests that you have to do to develop vaccines and therapeutics. So it's very hard to do some of this work in a laboratory, and at a university, that's very structured. So usually laboratories and universities, if they are developing a product, may contract out some of the work to these testing companies.

Q. All right. Now, you are familiar with a company called GenPhar?

A. Yes, I am.

Q. And its principal investigator, do you know him?

A. Um, Dr. John Dong.

Q. Thank you. And how did that come about? How is it that you became familiar with GenPhar?

A. So GenPhar -- Dr. Dong had written a grant proposal and submitted it to the NIH and it came to our division, NIAID.

Q. When, approximately, was that?

A. That would be approximately 2005.

Q. Okay. And was that grant ultimately provided to GenPhar?

A. The grant was ultimately provided. It was ultimately funded.

Q. How many different applications were submitted before the grant was awarded?

A. Can you clarify of his applications or all applications?

Q. I'm sorry. Yeah. Just the application of GenPhar and Dr. Dong.

A. Okay. He submitted this particular application to what we call a partnership request for applications. So normally there are approximately 250 to 300 applications to go to each of those partnership announcements. So his was one of those.

Q. Okay. And was that -- was that initial application actually awarded?

A. So in these partnership requests for applications, there is a certain dollar amount that's given to these awards. So you are limited in the number of awards that you can get under the partnership.

So if -- for instance, this is just an idea of it.

So if you have $100 million that's given to this partnership, you can award as many grants as possible until that $100 million is used up. So there is not a particular number of awards that you make. Everything depends upon how much money is requested in each grant application.

Q. Okay. So my question was: The initial grant application that GenPhar and Dr. Dong submitted, was it -- was that awarded?

A. It was awarded, but it was awarded at a lesser amount than what he had requested.

Q. And was there a second application that had to be submitted, then, to address that lower amount?

A. So -- yes. We had -- had an additional application to, yeah, that has that lower amount.

Q. Then the grant was awarded?

A. Then the grant was awarded.

Q. And what was the purpose of the grant? What was its mission?

A. The mission was to develop a vaccine for Marburg virus.

Q. And what was the -- I guess maybe I'm asking this inartfully, but what was the steps, what was the purpose of the grant? I know ultimately develop a vaccine, but was there a certain stage that it was supposed to progress to?

A. Yes. So the grant was awarded for four years. And you have different steps that you need to do in those four years.

So it would be starting a little bit more not basic research, but, you know, earlier on research, and then go on through the four years to, you know, see how the vaccine is being produced, to produce it under certain high quality conditions to make sure that the vaccine works in small animals and large animals, and to make sure that everything is in place, you know, to know that the vaccine is working for this particular disease.

You cannot test it in humans. It wouldn't be -- um, the vaccine causes a pretty severe hemorrhagic fever. A lot of people die from it. So you cannot test it in humans; you need to test it in animals. So you would test it in small animals, like mice and rats, and then go on to nonhuman primate testing.

Q. Do you remember the title of the grant?

A. I think it was Preclinical Development on a Marburg Vaccine.

Q. And what does preclinical development mean? Briefly.

A. So preclinical development means everything you need to do before you go into clinical testing, before it can be put into humans. So you need to test the safety of it, the composition of the vaccine, to make sure that it doesn't change. Like as you are producing it, you don't have mutations in it or something that changes the vaccine somehow, makes it less effective or makes it toxic; that sort

of thing. So you have to do different kinds of testing to make sure that the vaccine would be safe.

Q. Once you complete all that preclinical work, what's the next step?

A. The next step would be to go into a clinical trial with that vaccine.

Q. And who is it that approves that?

A. The FDA would have to approve going into a clinical trial. So you would have discussions with the FDA on whether your vaccine meets the FDA requirements to be safe and effective in preclinical in order for it to convince the FDA that it could be used and tried out in people.

Q. Does that involve a separate submission, then, to the FDA separate from the one that came to you --

A. Yes.

Q. -- for the preclinical one?

A. Yes.

Q. Have you been involved in that process personally?

A. I have been involved in that process for another application.

Q. How long does that take to get a new drug through from the completion of the preclinical work to FDA approval?

A. That normally takes a good 10 or 15 years. I mean, it's a long, long, very detailed process.

Q. All right. Now, this particular application that was

submitted by GenPhar, did it involve a certain specific vector or platform for the delivery of the vaccine candidate?

A. Yes. This particular application had something that was called a complex Adenovirus vector, so -- would you like me to explain the Adenovirus?

Q. In lay terms, if you can.

A. All right. Adenovirus is -- it's a very small virus particle, and -- but what it -- it's very naturally transmitted among humans. And usually by the time you are, you know, three or four or five years old, you have been subjected to Adenovirus infections in school. And you come home and you get a cold -- mainly causes colds -- so you get a cold and you pass it around to your family and then you are immune after that.

Q. And what's the biggest obstacle to the use of that common Adenovirus vector as a delivery mechanism for the vaccine candidate?

A. So one of the questions at that time, this particular grant used something called Adenovirus Type 5, which is one of those kind of viruses -- they have several types, but this was Type 5. It was a human virus. And so one of the questions was if you develop a vaccine using this vector, you know, if you are are already immune, if you've had these viruses when you are young and you have a cold, you may be immune to this vector. So you may not be able to be

vaccinated, so you would just --

Q. It would have no effect?

A. It would have no effect.

Q. Is that problem then overcome generally?

A. The problem may be overcome if you give a very large dose of a vaccine, or it may be overcome depending on how you administer the vaccine.

Q. And that's in general; not in particular with Marburg or any particular virus?

A. Correct.

Q. Whatever virus?

A. Whatever virus.

Q. Now, did you review the grant application that -- the revised grant application that GenPhar submitted that was ultimately approved?

A. Yes, I did.

Q. For what purpose?

A. I would be the Program Officer, so I would need to know what the grant is about in order for me to administer it.

Q. And did that grant application have budgeted amounts for consortium or contractual agreements?

A. Yes.

Q. Do you remember what they all are -- what they all were?

A. I don't remember the exact amounts off the top of my head, but --

Q. Is there something?
A. Yes. They were different contracts depending upon what was being done at the time.
Q. Okay. Is there a document I could show you that would have the exact amounts?
A. Yes.
Q. What would that be?
A. That would be the revised application.
Q. I'm going to show you what's been admitted into evidence as Government Exhibit 1. And I'll take that away from you.
Do you recognize that document?
A. Yes, I do.
Q. What is it?
A. Okay. So this is a document that's titled Preclinical Evaluation of a Trivalent Marburg Vaccine by Dr. Dong.
Q. Is that the revised application that you reviewed?
A. Yes, it is.
Q. Take a look, please, at page 8, if you would. There is a table in the middle. Do you see that?
A. Yes, I do.
Q. Are you familiar with it?
A. So the table is labeled Consortium Contractual Agreements. There is a list of different contractors with the cost.
Q. Okay. You've seen that before and reviewed it before?

A. Yes.

Q. Okay. Are the costs geared to any time periods or tasks?

A. So the costs --

THE COURT: Mr. Klumb? Mr. Klumb? Just a minute.

This exhibit was introduced some time ago. It was gone into by your first witness, Mr. Fato, a subsequent -- and he published, I don't know how much of it, but large portions of it. I told you then that you could publish these exhibits one time, you could talk about them in your closing argument, but you could not publish them repeatedly with each witness you call. And I've ruled that way one time when you tried to publish this very same document later through another witness, and I'm going to rule that way again. You publish this document through the witness, and I'm not going to permit it to be published again. It's in evidence, the jury can see it, you can call to their attention to any provision you want to, but to let each successive witness go in and call the jury's attention to parts of this exhibit, which can be published, in my opinion, is unnecessary, unwarranted, and I previously told you I wasn't going to permit it.

So let's go on to something else.

MR. KLUMB: Okay.

Q. Dr. Repik, close up the exhibit, if you would, please, and we'll ask you from memory. Do you remember what types of

subcontractor costs were in the grant proposal?

A. There were --

THE COURT: You can't -- you can't do that. These documents are in evidence. They are in evidence. And what you are trying to do, I don't know. Are we talking about Exhibit 1 now? Are we talking about another exhibit?

MR. KLUMB: What we are talking about what subcontracts were --

THE COURT: I'm asking you are we talking about Exhibit 1 or another exhibit?

MR. KLUMB: Well, I'm talking about the witness's memory of what subcontractor costs were included.

THE COURT: Where?

MR. KLUMB: In the grant award.

THE COURT: Is that Exhibit 1?

MR. KLUMB: It's multiple exhibits. There are -- there is the grant award itself; there is annual progress reports, which are budgets for the following year, all multiple ones, including Exhibit 1, Your Honor.

THE COURT: Okay. Well again, you've got multiple exhibits in evidence. I don't know of any exhibit having to do with the grant that hasn't come in evidence. I don't know of a single one that hasn't been published by a witness of yours.

In addition to that, I've made rulings under Rule

1002, which is the Best Evidence Rule, which says if you are going to prove the contents of a written document you have to have that written document. So we've got the written document, but you want to ask her memory, and you can't do that. The document is here. You can publish it. If you have to have an expert accountant come in and add things up, you can do that, but you can't publish it through every witness, and you can't prove the contents by her testimony. You have to do it by the written document.

And with those two rulings, let's move on.

MR. KLUMB: Okay.

Q. Regarding consortium or contractual costs in general, as the Program Officer, what involvement do you have in that work over the course of the grant?

A. So we would expect that the contracts would be -- they would be -- there would be a subcontract to this grant and a contract to this grant. And so we would expect the work to be done as it's laid out in the grant proposal.

Q. Okay. And you mentioned that there were dollar amounts attached to these that you could not remember. During the course of the grant, do you review any financial records to see whether or not the actual expenses are in line with the budget?

A. No. So the way that our NIH is set up, there is another group that reviews the finances and I would review the

scientific aspects of it.

Q. And for those subcontractors, whatever they are, do you review a report from each and every one of them during the course of the grant or just some of them?

A. So the progress reports they would review usually state, this is the work that was done, you know, according to the milestones of the grant. And certain ones have to be done by contractors; it could not be done by Dr. Dong or GenPhar.

Q. So if I understand it correct, some of the reports on the results of the contractor work is done by GenPhar and some they have to provide to you the source report?

A. Correct.

Q. Now, you mentioned a progress report. How often do those come in?

A. They come in annually.

Q. And did they produce those in this case, as well?

A. Yes.

Q. And did you review them?

A. Yes.

Q. For what purpose?

A. Program officers review the progress reports to make sure that, you know, progress has been made on the grant, to see if there are any glitches, to see, you know, how the progress is going. And so we don't see all of the raw data, but we see the reports that are submitted.

Q. Okay. And do you remember getting a progress report for year 1 of this particular grant?

A. Yes.

Q. How did you respond after you reviewed it?

A. So the grant, this particular grant, um, is focused on Marburg virus. Marburg is a hemorrhagic fever virus that causes severe hemorrhages, very similar to something that you may have heard on the news like E-Bola. It's the cousin to E-Bola.

So in the progress report for this particular grant, there was information in the progress report that referenced a vaccine that included an E-Bola vaccine.

Q. So how -- what did that prompt you to do?

A. So I -- after I reviewed the report, I contacted GenPhar and --

Q. Do you remember who it was that you contacted, talked to at GenPhar?

A. I think I talked to Jan Woraratanadharm.

Q. Pretty close. And then what did you tell her?

A. So Dr. Dong was not available at the time. I think he was on a business trip. And so I told Jan that, you know, this progress report, you know, while it was very interesting, I would like to, you know, have the progress report really focus on the grant proposal itself, you know, what NIAID was paying for this particular project. And so --

Q. Which was, again, for what purpose?
A. For the Marburg virus.
Q. Okay. Did you -- did you raise any other issues about the progress report with her besides the fact that it made reference to an E-Bola report?
A. So there -- there were a couple of other notes that I took on the progress report.
Q. What were they? What were those other issues?
A. So one of them, the progress report had mentioned using some primary human cells. So I raised an issue with that. This grant -- this particular grant did not have the approvals to use any human material.
Q. Okay. What other issues, if any?
A. I know there was another issue, and I can't remember it off the top of my head.
Q. Is there something that would refresh your recollection?
A. Yes.
Q. What would that be?
A. I took notes during my conversation with Jan.
MR. KLUMB: The Court's indulgence, I'm just going to mark this for the record. Having previously shown it to counsel.
Q. I'm going to show you what's been marked for identification as Government Exhibit 214. It's a photocopy of a document. Do you recognize it?

A. Yes, I do. These are the notes that I took during my conversation with Jan.

Q. Would you review the notes to yourself, please, and then tell us whether or not that refreshes your recollection about the items that you raised with Dr. Woraratanadharm?

THE COURT: Any objection? Ms. Parham? Any objection?

MS. PARHAM: Not to her refreshing her memory. I object to the notes coming into evidence, but not to refresh her memory.

MR. KLUMB: I'm not going to offer them.

Q. Are you done? You reviewed them?

A. Yes.

Q. And does that refresh your recollection?

A. Yes, it does.

Q. Take that away.

And what other issues did you raise with Dr. Woraratanadharm?

A. So there were some personnel changes that were not there on the original grant application.

Q. And anything else?

A. And -- I'm sorry. I'm just blanking out again. Some of the milestones were changed, also, and the order of the milestones were changed.

Q. What did you tell her about those?

A. I said that for this particular kind of grant they need to contact the program officer to get approvals to change the mile -- the order of the milestones.

Q. Okay. Now, did you have a conversation with anyone else at GenPhar about those issues that you just discussed, that you told us about that you discussed with Dr. Woraratanadharm?

A. No, those were my personal notes that I took, and I discussed them with Dr. Woraratanadharm and asked if they could be addressed.

Q. And did you talk to anybody else besides her at GenPhar about those issues?

MS. PARHAM: Asked and answered, Your Honor.

THE COURT: I thought you just asked her that about two questions ago, but let's get an answer.

Q. She was the only person that you talked to at --

A. Dr. Dong -- I called to talk to Dr. Dong, but he was not available then. So I only spoke with Dr. Woraratanadharm.

Q. And never talked to anyone else?

A. I didn't talk to Dr. Dong personally. He was on a business trip.

Q. Okay. Now, when did the funding end for this particular grant? Do you remember what year?

A. So the funding went from -- normally it was a four-year grant in 2006 to 2010, and then there was a one-year no cost

extension on it.

Q. And just so we understand what that means, what is a one-year no cost extension?

A. That means you get an extension to do the work for one year, but there is no additional funds for that.

Q. So the actual funding, in other words, GenPhar's ability to get money for the grant would have ended what year, then?

A. It would have been five years. So that would have been 2011.

Q. Now, did there ever come a time when you visited GenPhar here in South Carolina?

A. Yes, I did.

Q. And when would that have been?

A. So that would have been May, and I believe 2009, '10.

Q. Is there something I can show you that would refresh your recollection about that?

A. Yes, there would.

Q. What would that be?

A. I have notes from that -- from my site visit.

THE COURT: Do you remember coming to South Carolina?

THE WITNESS: Yes, I do. It was wonderful.

THE COURT: Let's ask her some questions about it and see if you can remember it. That's the first requirement to refresh somebody's memory, if they don't have a memory.

So let's cover that base first.

MR. KLUMB: Thank you, Judge. I'll do my best.

Q. Do you remember being interviewed by federal agents for the first time about GenPhar?

A. Yes, I do.

Q. Was your trip to GenPhar before or after that?

A. My trip to GenPhar was after my conversation with federal agents.

Q. Is there anything you can think of that would fix -- help you fix the time or the year that you came off the top of your head?

THE COURT: I thought she said May of '09. That's what I wrote down.

MR. KLUMB: I thought she said --

THE WITNESS: I said '09 or '10, but it would have been in that timeframe.

MR. KLUMB: Okay.

Q. Did you go to their existing facility at the time?

A. Yes.

Q. And describe it for us.

A. So the existing facility where the work was being done was generally -- it looked like, you know, a nice building. It was just generally a building that you would normally see driving down any street. And inside the building were laboratories. So they had office space, they had laboratory

space, and it looked like a not -- a nondescript kind of a building. I mean, it was just a nice building.

Q. Okay. And did you see their new construction?

A. Yes. I asked to see the new construction. I knew that there was new construction, and so --

Q. How did you learn that, first of all?

A. So in the original grant proposal, there was mention of new construction. And I know, you know, just from conversations with Dr. Dong that there was new construction going on for a new building.

Q. Okay. So you went and saw it. Who went with you?

A. Dr. Dong.

Q. Anyone else?

A. I don't believe so. Just Dr. Dong and myself.

Q. And can you describe the new building for us, please?

A. So the new building was a bit a ways from the current -- their current location. And so it was a beautiful building. It was a huge brick building, and very nice setting.

And when I walked in the building, there were double, like a -- not a winding staircase, but a staircase that's going up from the main hall where you came in. And they had a beautiful setting. It was like a park-like setting.

One side of the building was to be designated as laboratory space for the workers in the building, and the

other side of the building was to be designated as what's called a manufacturing facility where you can do manufacturing under, like, FDA regulations.

Q. And how would you describe it?

A. I think I wrote a note to Dr. Dong and I said this was the Taj Mahal of scientific buildings. It was really beautiful.

Q. How about the floors?

A. The floors were -- normally in the buildings I have been in, the floors are just concrete, or, you know, nothing special. These had kind of like granite tiles to them. The lab benches were this beautiful wood, they weren't the regular steel that normally labs are. So, I mean, it was a very beautiful building.

Q. So did the nature of the building, as you observed it, prompt you to ask Dr. Dong any questions about it?

A. So I did ask, you know, Where are you getting the money to build this building?

Q. And what did he tell you?

A. He said he had investor funding for that.

Q. Did -- during the period of time that you supervised this grant, did anyone from GenPhar ask you if you could use leftover grant money to pay for that building?

A. No.

Q. Did Dr. Dong give you any indication that day that that

was the case?

A. No.

Q. Had you learned that GenPhar was using leftover grant money to pay for the building, what would you have done?

A. I would have talked to my supervisor first, and also talked to the Grants Management people. So the Grants Management people at NIH are the ones that are concerned with the spending.

Q. Okay. Now, let me show you what's been previously marked for identification as Government Exhibit 32 but not admitted.

Show you something different. I'm going to show you a large pile of paper marked for identification as Government Exhibit 169.

THE COURT: Do you have anything further of this witness?

MR. KLUMB: I'm waiting for counsel to review the document, which is sizeable, but was in our exhibit list and previously provided.

MS. PARHAM: I'm not sure the relevance of all this, but I'll just wait and see.

THE COURT: All right. Let's proceed.

Q. Was there any work under this grant that had to do with toxicity in biodistribution studies?

A. Yes.

Q. What work was supposed to be done?

A. So the work -- when you develop a vaccine, one of the requirements, the FDA requirements is to do a biodistribution study and a toxicity study in animals. Would you like me to explain what those are?

Q. That's good enough.

And was that work in fact done as far as you knew?

A. Yes.

Q. And how was it that it was reported to you?

A. So in -- in progress reports, there was mention that bio -- that toxicity and biodistribution studies were done on the M8. The vaccine candidate was called M8.

Q. Okay. And did you receive any reports?

A. So yes. I had asked for reports of this.

Q. Who did you ask?

A. Again, it was an e-mail that I had sent, and I had asked for reports. And I think I had sent them to Dr. Dong or to Jan.

Q. And then did you subsequently get the reports?

A. I did.

Q. Okay. Let me show you, then, what's been marked for identification as Government Exhibit 169, which is a very large document.

A. Um-hum.

Q. Take a look at the front page, if you will, and tell us whether you recognize that.

A. Yes, I do.
Q. What do you recognize it to be?
A. So this is called a final report of EBO7MD vaccine.
Q. Is that one of the reports that you received?
A. Yes. I received this by e-mail, like a PDF e-mail.
Q. Okay. And at the time -- well, strike that.

MR. KLUMB: At this time, then, I would offer into evidence Government Exhibit 169.

THE COURT: Yes, ma'am?

MS. PARHAM: No objection.

THE COURT: No objection. Any objection? Okay. Without objection.

(Thereupon, Government Exhibit Number 169 was received in evidence.)

Q. Now, you just told us a little while ago that after the first year progress report you noticed that there was an E-Bola test that had been reported.
A. Correct.
Q. And now, is this for Marburg or something different?
A. So this report is a toxicity study that has a combined E-Bola/Marburg vaccine. So it's two vaccines in one.
Q. And do you happen to know, was Dr. Dong working with another federal agency at the time on an E-Bola/Marburg vaccine?
A. So he had a contract with USAMRIID, which is an Army

contract, to work on an E-Bola/Marburg vaccine.

Q. Now, at the time that you received this report, did you notice that it was for both E-Bola and Marburg and not --

THE COURT: Now again, again, there has been no objection made, but anybody that looks at this exhibit kind of shudders a little bit because it would probably take until next Friday to read it. But still, Rule 1002 applies to it, just as it does any other written document. The contents of which you wish to prove, you must prove it with the written document. And it appears to me that at least the last question was an attempt on your part to get her to say what was in the report, and she can't do that. She can publish it, but she can't summarize what's in it. That's what the Best Evidence Rule is all about.

And let me see if I can put my hands on it, and I'll read it to you, just in case you haven't read it in a while. Let's see now. It's a very long rule. "To prove the content of a writing, recording or photograph, the original writing, recording or photograph is required." That's the Best Evidence Rule.

Ladies and gentlemen, I would like to finish this witness, but I don't want to deprive you of lunch any longer. And so let's be in recess until 2:30. We are getting started a little late. If you come in late, we'll accommodate you, but try to be back at 2:30 if you can.

We'll be in recess.

(Thereupon, the jury exited the courtroom.)

THE COURT: And I don't know what you plan to do with this document, I certainly -- if you want to read it, I don't know what we'll do. Obviously, the way the Rules are written, 1002 has to do with the Best Evidence Rule, 2006 has to do with summary. And obviously that summary provision is in there for obvious reasons, and this exhibit would certainly apply to it. It doesn't say I can make you summarize it; it says you may summarize it. So let's see what happens, but I certainly hope we don't have to take the time of the jury to read that document to them.

MR. KLUMB: Your Honor, I was just planning on showing her, publishing a couple of pages.

THE COURT: Say what?

MR. KLUMB: I planned on only publishing a couple of pages, a few pages.

THE COURT: That's fine. And the defendant, bear in mind, if they publish a few, you can make them publish additional pages that the jury needs to hear to fully understand what they are hearing. You understand?

MR. MACE: Yes, sir.

(Thereupon, there was a lunch recess.)

THE COURT: You can bring the jury out. Come back around, please, ma'am.

(Thereupon, the jury returned to the courtroom.)

THE COURT: All right, sir.

MR. KLUMB: You can be seated.

Q. Let me just back up and take care of some housekeeping, Dr. Repik.

Recall that you could not remember whether your site visit was in 2009 or 2010. Let me show you what's been marked for identification as Government Exhibit 194, previously shown to counsel, and I would ask you to take a look at that and review the document and then tell us whether or not that refreshes your recollection as to the time of your visit.

THE COURT: Any objection?

MS. PARHAM: No, sir.

A. My visit was on May 24th through 25th, 2010.

Q. By the way, you indicated that Dr. Dong told you that the building was funded with investor money. Did he give you any specifics about the investor or not?

A. Um, I asked who the investor was. He didn't name any names, but he said it was someone from Germany, and they had made some money through railroads. And that's all I know.

Q. Okay. Now, I think when we left we had just introduced Government Exhibit 169 into evidence.

MR. KLUMB: And so if the Court please, I would like to publish two pages from it.

THE COURT: Sure.

Q. Okay. Can you see that up there okay, Dr. Repik?

A. Yes. Yes.

MR. KLUMB: Zoom in on the middle of the page.

Q. First of all, what is -- would you read, please, the title?

THE COURT: Why don't you read it, sir?

MR. KLUMB: Be glad to. Sorry, Your Honor.

It states: "Final Report, EBO7M8 vaccine. A repeat intramuscular dose toxicity study in the New Zealand white rabbit test article EBO67MA. Sponsor GenPhar. Testing facility, Bridge Global Pharmaceutical Services. Study completion date, May 15th, 2009."

Q. Did you notice that the article tested when you received this report was for both E-Bola and Marburg viruses?

A. Well, the E-Bola is obviously E-Bola, and I knew that MA is Marburg.

Q. Did your grant cover -- the grant that you were administering -- cover both E-Bola and Marburg?

A. No. Mine only covered Marburg.

Q. Were you aware of another grant that covered E-Bola and Marburg?

A. So that would be a contract that was through DOD, through the Army.

Q. Through the Army? Okay. Thank you.

Now, let me show you what's been -- I'm sorry -- page 5 of that exhibit.

MR. KLUMB: And I'll publish, I guess, this page. It's a quality assurance statement for BO7M8 vaccine. A repeat muscle low dose toxicity study in the New Zealand white rabbit. And it indicates in the middle of the page that the draft report and raw data was audited on March 14th to 22nd, 2007. The date reported by the study director was March 22nd, 2007. And management, the protocol amendment audit was April 11th, 2007. The date reported was April 12th, 2007. And the final report post-audit and amendment audit was May 4th, 5th and 7th, 2009. Date reported May 8th, 2009.

Q. Doctor, when you reviewed this report after it was provided to you by GenPhar, did you notice that the report summarized test results that had been done two years earlier?

A. Correct. Yes.

Q. Did you notice that when you reviewed it?

A. Yes.

Q. Okay. And what -- what were your conclusions about that?

A. So my conclusions -- well, one, I was wondering why the final report date was several years after the initiation of the study, and --

Q. Did you ask anyone at GenPhar?

A. I did.

Q. And what --

A. I believe I also asked Jan that question, and Dr. Dong maybe. And they just said they hadn't received the final report yet. So I said, You really need to get the final report.

Q. Thank you. Now let me show you what's been marked for identification as Government's Exhibit 168 that I have previously shown to counsel.

Do you recognize it?

A. Yes. This is a final report for the same E-Bola/Marburg vaccine for a dose vital distribution study in New Zealand white rabbits.

Q. Was that report provided to you?

A. Yes, it was provided to me at the same time the tox report was.

Q. By whom?

A. By Jan again.

MR. KLUMB: At this time I would offer Government Exhibit 168.

MS. PARHAM: No objection.

MR. DICKSON: No objection, Your Honor.

(Thereupon, Government's Exhibit Number 168 was received in evidence.)

Q. Incidentally, this company, the Bridge Global Pharmaceutical Services, are you familiar with them?

A. I know that they are a contract research organization, or CRO. They do -- they are recognized as a legitimate CRO for biosafety testing for FDA products. Gone through FDA approval.

Q. Do they run a GLP lab or not?

A. Yes, they would run a GLP lab.

Q. When you visited the GenPhar facility in May of 2010, could you tell whether or not GenPhar's facility was a GLP lab?

A. No, I didn't -- I didn't review any of the -- for a GLP lab, you need to have a lot of documentation, a lot of SOPs, that sort of thing.

So when I visited GenPhar labs, I was not there to do an audit; I was there really to talk about the vaccines that were being produced. I didn't request to see any of their SOPs or anything like that, but --

Q. Based on your --

A. -- you know --

Q. Go ahead.

A. I'm sorry. It seemed to me to be a company that was doing, you know, both research and development, but it wouldn't probably be the extent of the documentation that a company like a CRO would have.

Q. Did you conclude that they were capable of doing GLP work in their lab?

A. I'm sorry, I can't even respond to that. I didn't see any of their training. They would have to have training records and all of that sort of thing. So I didn't request to see any of that.

MR. KLUMB: Thank you. That's all I have, Your Honor.

THE COURT: Cross-examination.

MS. PARHAM: Thank you.

CROSS-EXAMINATION

BY MS. PARHAM:

Q. So you didn't see any clean rooms; you weren't even there for that type of evaluation?

A. Correct.

Q. So you don't know whether they did or didn't?

A. Right.

Q. Now, these grants that you work on, they have significant peer reviews before they are granted to a grantee?

A. Correct.

Q. And so this NIH Marburg Grant had that same type of process?

A. Correct.

Q. And aren't there a good number of -- how many experts sit on that peer review process?

A. So for this particular peer review process, it was a partnership grant, and so the whole panel probably were 50 or

more people. And they would all have different backgrounds. Some of them would be viruses; some of them would be bacteria. So they would have a different background, but they would also have background in process development and product development.

Q. And those are all considered experts in their field --

A. Correct.

Q. -- those 50 people?

And so they would evaluate GenPhar's grant and other proposed grants to see which ones they wanted to fund?

A. They don't have any decision in the funding. They have a decision in how -- how well the application is presented, you know, what -- if it looks feasible, if it's an important project, so --

Q. And they would have done that with regard to this grant?

A. Correct.

Q. Now, what percent of the grants are actually funded, you know, if you take all the applicants and then you -- approximately what percentage are funded?

A. Like I mentioned before, for this particular kind of process, it's not a particular number that's funded. So it's -- for this particular process, for this partnership application, there was a certain amount of money. And they try to fund as many for that amount of money as they can.

So those kind of grants are all on different stages

of process development. So the ones that are later stage would cost more. So if we had a lot of those, then there would be fewer grants funded in that pot of money.

Q. And the later stage actually involves vaccine production?

A. Right. Any --

Q. Just much more expensive than getting there?

A. Correct. So GMP production and all of these biosafety testing with a CRO cost more money.

Q. And I guess logically you would rather have several viable vaccines to be tested than try to put all your money into one to be produced?

A. Correct.

Q. And so that's why a lot of the earlier stage grants would be funded, because you have more shot at getting a good vaccine?

A. So when these grants are reviewed, they are not reviewed saying that we want a particular vaccine; they are reviewed basically on the science. And then the program officers also can have -- they have an opinion after all the grant -- all the review process is completed. And the program officers also can say, you know, We have very little grants in this kind of portfolio or to this product. You know, if there is a way to try to get that grant funded, we would try to do that.

Q. When you say it's more of a collaborative -- I can't

remember which word you used -- what's the significance between that as opposed to other research grants?

A. The significance of this particular grant?

Q. You said that -- I'm not sure which word you used, but where there is input from the scientists?

A. So this was a cooperative agreement grant. This particular grant was a cooperative agreement grant.

Q. So the scientists have input as the research develops?

A. So the scientists always have the input. In a cooperative agreement grant, the program officer has significantly more input than a regular smaller RO1 project.

Q. And that would have been you?

A. That would be me.

Q. So when this grant was submitted, these experts looked at it and they believed the research was well-founded and it was a good grant?

A. Correct. So they thought it was a good grant. And it had gotten a particular score. And it didn't go through on that particular funding round because money for all the other scores -- the money was tending to be used up on that particular pot of money.

Q. And so then once the grant is funded, or at least it's scored by the experts and NIH decides to fund a grant, then you become the Program Officer for the grant?

A. Correct.

Q. And you review primarily the science behind the milestones and the grant?

A. Correct.

Q. And you said there is another division of NIH that kind of looks at the finances.

A. Correct.

Q. And what are they called?

A. So that's Grants Management, Grants Management branch.

Q. And so was there a particular Grants Management Officer assigned to this grant?

A. There always is, yes.

Q. Okay. And who would that have been? Do you remember?

A. I think -- so the Grants Management Officer -- the Grants Management officers are assigned to grants based on geography, all right? So certain ones are assigned to different states, and then those switch around. So I think this particular grant had two or three. I think Don Mitchum was one and Penny Williams may have been one. So they --

Q. So Don Mitchum, Penny Williams. Do you recall any other names of any of those financial managers?

A. Not offhand I don't.

Q. All right. And so what is their role as to what your role is?

A. So my role is basically to look at the science, see if the science is feasible, see that in the progress reports

that the work that is supposed to be done looks like it's being done with not too many glitches. And if there is a glitch, we can switch things around a bit to work around that.

The grants management portion of this is to look more at the finances, you know, to see that things look pretty reasonable. And, you know, if there is questions on animal use or any other kind of use, they handle those, as well.

Q. And so even though you are concerned with the science, you know enough about this science, you also look at whether the cost to achieve a certain science appear to be reasonable to you?

A. Correct.

Q. I mean, in addition to the financial side also looks at that?

A. Right.

Q. And with regard to this grant, you believe that it was reasonable as far as cost associated with scientific progress or not?

A. So if I can -- I mean, when the grant was first reviewed, it came in as a certain cost, and looking at it scientifically, also. So some percent was given -- a critique is given of the grant proposal.

So this particular grant, they had some questions

about the platform, the Adenovirus platform, and it didn't make the first cut, so -- and the cost looked a little bit unreasonable at that point.

And so what we were able to do is to cut down on the actual science that was being proposed because it seemed to be too far advanced for wherever this product was at the time. And so some of the milestones were cut and the cost was cut.

Q. And you did that?

A. So that was done on, it's something called end of the year funding. So I had proposed -- I had recommended this grant for end of year funding. So the money for that particular partnership was used up. But when NIH funds grants, there is always a pot of money that NIH gets to fund grants, and there is always a little bit left over. So at the end of the year --

THE COURT: Excuse me. I don't mean to interrupt you, but she asked you a question and the question was, "And you did that," talking about cutting the cost.

THE WITNESS: I recommended it.

THE COURT: Okay.

Go ahead.

Q. And was that before the grant was even funded or was that after a certain year? When did that take place?

A. That was before the grant was funded.

Q. All right. So then there was a revised application to meet your concerns and that's the application I guess that the Government was showing you?

A. That's right.

Q. So that's after it was revised?

A. Right.

Q. But in that application, those are basically projected research and projected costs that they are going to do over the life of the grant?

A. Correct. So they have a budget for every year.

Q. And is that also the same with the progress reports, they tell what personnel was used the past year, but they also tell what kind of science they plan to achieve for next year?

A. Correct.

Q. And so those are kind of projected science and milestones?

A. So they are -- generally for this type of grant the milestones are there. And they are supposed to be working through the milestones, unless there is a glitch in them, we can switch those around.

Q. And if there is a glitch, as you call it, then you would work with the company to try to find a way around that glitch?

A. Correct.

Q. Because your goal is to have the science done?

A. Correct.

Q. And in your opinion, was the science met based on the milestones you read and the information you received from GenPhar --

A. Correct.

Q. -- throughout the course of the grant?

A. Throughout the course of the grant it looked like it was, the work was being done pretty much on track. There were -- there were some glitches, there were some holdups in some areas, but generally it seemed to be progressing pretty well with the progress reports that I received.

Q. And one of those glitches was even the purchase of a certain bioreactor. And they submitted to you and asked that they purchase something smaller, some other equipment?

A. Correct.

Q. And that's a typical example of a glitch?

A. Well, they decided they needed a different piece of equipment. And so it was still within the cost of the grant, the grant funds did not increase, so they re-budgeted certain areas to get that piece of equipment.

Q. Right.

A. But they had to get NIH permission to do that.

Q. But they can re-budget up to 25 percent without permission?

A. For this particular type of grant, they do need

permission. And this is a cooperative agreement grant. This is not a normal NIH grant.

Q. But Mr. Fato would have equal knowledge about this particular kind of grant?

A. Correct.

Q. Okay. And there were, I believe, facilities and administration costs of 76 percent for years 2, 3 and 4?

A. Yeah. So the flows in administration, those numbers are, I guess, established outside of our grant mechanism. They are established another way.

Q. And if the application -- and even in the progress reports, there is a monetary amount next to each milestone?

A. Correct.

Q. And so once a grantee achieves that scientific milestone, then there -- that's when the next piece of monetary budget would be released?

A. All right. So the program officers review the grant proposal of the, um, report -- the progress report, I'm sorry, and it looks like it's, you know, they were pretty much on track, the program officer for this particular type of grant says, you know, These milestones seem to have been met or they are near being met and we give approval for the next money for the next year.

Q. Okay. And so whether that money is released is dependent on whether the scientific milestone has been achieved?

A. Correct.

Q. And that's what it is based upon?

A. Correct.

Q. All right. Now, with regard to this bridge report -- let me go back.

With regard to the kind of problem that you said could be present in an Adenovirus Category 5 type of vaccine, because you know our bodies have been -- I can't remember the details -- but Dr. Dong and GenPhar found a way around that?

A. So when he wrote the grant proposal, it -- he didn't really say the way around it in the grant proposal itself. So some of the reviewers questioned that and said, you know, This may not work if you need a booster shot since you are already immune to the Adenovirus and the booster shot might not work and you might not get what you need to get protected against Marburg. In the revised proposal, that kind of thing was addressed.

Q. All right. And so he addressed what your concerns were was that people might have to have a booster shot, and he actually identified, I believe, six or seven patents that the company had regarding this particular way around it, so to speak?

A. Well, they had patents on different kinds of things. But the way around it was they found that if you get a higher dose of a vaccine, you can get a way around it. So those

were part of the grant proposal for them to test whether that would work.

Q. And that actually tested whether that would work in monkeys?

A. Correct.

Q. And it worked?

A. It seemed to work, yeah.

Q. And the monkey studies, based upon that new theory or the new patent, was 100 percent successful?

A. Correct.

Q. And you were pleased with the scientific progress of this grant?

A. I was.

Q. And the next phase, of course, would have been to go to human trials?

A. There would need to be more monkey studies, I think. It's important to know the type of dosing to give, you know, how much of the vaccine to give, if you are going to give a booster, how far apart the booster is, it was a week apart, you know, two weeks apart, three weeks apart, and to look at the immune response that you develop in this. So that still was being developed.

Q. And it's not unusual for science to change during the pendency of a grant, is it? I mean, not scientific milestones, but I guess research can take scientists

different places?

A. Correct.

Q. And so is it unusual for a grantee to want to change, for example, you know, who performs a certain study for them, or I mean, they can change that during the course of the grant?

A. Yes. So sometimes that happens. Sometimes a company disappears, it goes down, and so they have to have another way of testing it or another contract research organization to do the testing. So it's still -- it's the same work, but if it could be done by somebody else that would also be, you know, a reasonable --

Q. And if they could find someone to do it cheaper, the same stuff, would that also be reasonable science or still good in your opinion?

A. Yes. And that is done in many cases.

So normally you would get quotes from different companies. And just like if you were going to remove a roof, you look at the quality of the work and the amount of money that is proposed to do that work, and you try to make a scientific decision saying that, you know, this can be done a little cheaper and the quality of the work is the same, then, you know, scientists would maybe go with the cheaper route as long as the quality was there.

Q. And that's -- there is nothing wrong with that as long as the quality is there?

A. Correct.

Q. Now, we've seen this NIH Policy Guidelines Manual. Once that manual was published in 2003, aren't there monthly, like, revisions to that manual that NIH puts out over the course of a year, or years?

A. Yeah. I'm not sure --

Q. Okay.

A. -- of that.

Q. So you are not sure about how many revisions there are to the --

A. No, I'm not sure what manual you are referring to.

Q. Okay. Now, what is a GLP lab?

A. So GLP means good laboratory practices, and it's a laboratory that again has a lot of quality control. So you have standard operating procedures to do all different things. You have -- like if you are going to incubate something in the refrigerator or a water bath, if you -- say you are going to do it at 37 degrees, plus or minus two degrees, it needs to be that, okay? If you are pipetting a certain amount of something, you need to have your pipettors calibrated.

So there is a lot of calibrations for all of the pieces of equipment. There is training for everybody who is using any of those pieces of equipment. There is specified maintenance of each piece of equipment to make sure that it's

performing at the top caliber that it needs to be. So there is a lot of paperwork, a lot of documentation to do something in GLP.

Q. All right. And so to be a vaccine production, or if they were trying to have a new facility to be a GLP, it's a highly technical type of facility that has to have a lot of checks and balances?

A. Correct.

Q. Including clean rooms and things like that?

A. Correct.

Q. All right. And so with regard to this particular NIH Marburg Grant, you believe that the science was achieved yearly?

A. It seemed like the science was being achieved yearly. There were some changes and we agreed to those changes, so --

Q. And you thought the finances were reasonable in relation to the science, that the work that was being done with regard to the money that was being charged?

A. Correct.

MS. PARHAM: That's all I have.

MR. DICKINSON: May I ask a question?

THE COURT: Say what?

MR. DICKSON: May I ask my question?

THE COURT: I didn't know Ms. Parham was through. Certainly.

MS. PARHAM: I'm sorry.

MR. DICKSON: Thank you, sir.

CROSS-EXAMINATION

BY MR. DICKSON:

Q. You were not familiar with any personal finances of GenPhar, Inc., are you?

A. No, I'm not.

Q. You don't know how much the shareholders have invested in the company?

A. No. I have no idea.

Q. How many shareholders there were?

A. Pardon me?

Q. Or how many shareholders there were?

A. No.

Q. Okay.

MR. DICKSON: Thank you.

THE COURT: Redirect?

MR. KLUMB: Thank you, Your Honor.

REDIRECT EXAMINATION

BY MR. KLUMB:

Q. Dr. Repik, you said that there was some changes and you agreed to them. What were they?

A. So when the grant was proposed, they proposed to inoculate or, you know, to vaccinate with an intramuscular route. So if it's a needle, it would be a needle stick,

essentially, to deliver the vaccine.

And one of the -- you know, scientifically it seemed like, you know -- there was some studies that were done and it seems like if you gave the vaccine instead of an injection in the arm or an injection wherever, that if you gave it by, say, a spray up the nose, like a flu mist or something like that, but they can help overcome this problem, the potential problem of --

Q. So one change was the method of administration?

A. Yes. So originally it wasn't proposed to look at those other alternative methods, so it would be a different kind of delivery group. So whether it's a tablet that you might -- not a tablet -- but say like a Listerine mint strip that just melts in your mouth, that could be a vaccine delivery system, or a spray up the nose, like flu mist.

So we agreed to, you know, not change the whole direction of the whole thing, but to include those kind of tests in the monkeys, you know, to see if that would be a proper vaccination or delivery system.

Q. Did GenPhar get your permission for that?

A. They got my permission for that.

Q. You indicated that the milestones were achieved. Was one of the milestones GMP production?

A. Correct.

Q. Could you describe briefly for us in layperson's terms

what that is?

A. So GMP means good manufacturing processes. And that's again very, very strictly regulated. And they have different contract research organizations usually that will do GMP manufacturing. So manufacturing is different than good laboratory practices, okay? There are different standards for manufacturing, but they have to be -- have all these same -- everything has to be calibrated. Everything has to be checked over and over. You have to make sure that the product you are manufacturing is what it says it is. And so there is a lot of tests to make sure of that.

So you have probably cullin sequence to make sure that the genome of the virus doesn't change, that it's pure, that there is no mutations put into it as the virus is replicating, that it's safe, there is -- it's safe for everyone to use, it's not toxic. So there are a whole slew of tests that have to go through GMP manufacturing, you know.

Q. Okay. Is that necessary to start a clinical work with humans?

A. Usually if you are going to do clinical work, you can -- you may be able if you -- you would need to have FDA approvals first off.

Q. Okay. And you indicated it was a milestone. Was GenPhar able to reach that milestone? Did they actually get GMP production of their vaccine candidate?

A. So I don't believe that they have GMP production on the vaccine candidate.

Q. Thank you. Now, you also asked -- told Ms. Parham that if a subcontractor on a cooperative agreement can do it cheaper to maintain the same quality, the cooperative agreement recipient is free to go ahead and do that, right?

A. Correct.

Q. To the extent that there is a cost savings there and there is leftover money, do they get to use, then, that money for any purpose?

A. So if -- so the grant is awarded with money in certain categories. And so you have money that goes to supplies, money that goes to salaries and that sort of thing. And so they can re-budget money. If they can do something cheaper, they don't get anymore money, but they can re-budget money and put it into salaries or publications and that sort of thing.

Q. Could they put it towards different research, research, say, of a Dengue virus?

A. No, they could not.

Q. How about travel and entertainment?

A. No. I mean, so --

Q. How about a building?

A. Definitely not.

Q. How about lobbying?

A. No.

MR. KLUMB: Thank you. That's all I have.

THE COURT: Anything further?

MS. PARHAM: No, sir.

THE COURT: Okay. Thank you, ma'am. You are excused.

***** ***** *****

I certify that the foregoing is a correct transcript from the record of proceedings in the above-titled matter.

Amy C. Diaz, RPR, CRR November 24, 2014

S/ Amy Diaz